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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,226	06/29/2001	Eric J. Benjamin	AM100155	9422

35139 7590 03/05/2007

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EXAMINER	
KANTAMNENI, SHOBHA	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	09/896,226	BENJAMIN ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

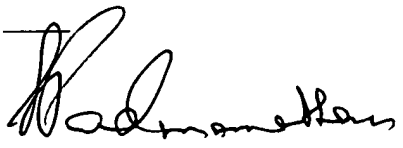
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 32-42.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see page.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

Continuation of 11:
Applicant's arguments have been fully considered, but not found persuasive, and the rejections made in the final office action are MAINTAINED.

The rejection of claims 32-42 under 35 U.S.C. 103(a) as being unpatentable over Raveendranath et al. (WO 9919293, PTO-1449 submitted September 18, 2001), in view of Sawicka (Pharmazie 1991, vol.46 page 519-521, PTO-1449 submitted September 28, 2001), and further in view of Gibson et al. (US 5,811,120, PTO-892) is MAINTAINED.

The rejection of claims 32-42 under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (EP 802183, PTO-1449 submitted June 10, 2005), in view of Sawicka (Pharmazie 1991, vol.46 page 519-521, PT0-1449 submitted September 28, 2001), and further in view of Gibson et al. (US 5,811,120, PTO-892) is MAINTAINED.

Response to Applican't Arguments:

Applicant arguments have been considered, but not found persuasive because Raveendranath et al., and Miller et al. teaches that the compositions therein containing indol compounds are formulated with wetting agents such as sodium lauryl sulfate, and glidants such as magnesium stearate. Raveendranath et al., and Miller et al. do not teach the specific amounts of glidants, and wetting agents as in the instant claims. Gibson et al. teaches that raloxifene hydrochloride which contains benzothiophene, two phenolic hydroxyl groups has low solubility in water, which limits its bioavailability. Gibson teaches that raloxifene in combination with a hydrophilic carrier composition which contains surfactant, binder, lubricrant has increased solubility. Gibson also teaches such specific range of amounts of a wetting agent, and a glidant as instantly claimed in a pharmaceutical composition comprising low soluble, hydrophobic compound such as raloxifene. It would have been obvious from the teachings of Gibson et al. to employ specific amounts of wetting agents, glidants etc. in the composition taught by Raveendranath et al., and Miller et al. because the instant compound 2-(4-Hydroxy-phenyl)-3-methyl-1-[4-(2-piperidin-1-yl-ethoxyl)-benzyl]-1H-indol-5-ol, and raloxifene are both hydrophobic compounds, and would be expected to have similar solubility in water. Thus, one having ordinary skill in the art at the time of the invention would have been motivated to employ the specific range of amounts of a filler, disintergrant components, a wetting agent, a lubricant, and a glidant in a pharmaceutical composition with reasonable expectation of obtaining a pharmaceutical composition with increased solubility, and optimum bioavailability of 2-(4-Hydroxy-phenyl)-3-methyl-1-[4-(2-piperidin-1-yl- ethoxyl)-benzyl]-1H-indol-5-ol because Gibson teaches that solubility of low soluble, hydrophobic compound, containing 2 phenolic hydroxyl is increased in the compositions therein.

Further, optimization of result specific parameters such as amounts of known ingredients in a compositions is routine to a person of ordinary skill in the art.